

## Food and Drug Administration, HHS

## § 1302.02

that the results of such inquiries will be treated by the employer in confidence will be explained to the employee.

[40 FR 17143, Apr. 17, 1975]

### **§ 1301.91 Employee responsibility to report drug diversion.**

Reports of drug diversion by fellow employees is not only a necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area. The employer shall inform all employees concerning this policy.

[40 FR 17143, Apr. 17, 1975]

### **§ 1301.92 Illicit activities by employees.**

It is the position of DEA that employees who possess, sell, use or divert controlled substances will subject themselves not only to State or Federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.

[40 FR 17143, Apr. 17, 1975]

### **§ 1301.93 Sources of information for employee checks.**

DEA recommends that inquiries concerning employees' criminal records be made as follows:

*Local inquiries.* Inquiries should be made by name, date and place of birth, and other identifying information, to local courts and

law enforcement agencies for records of pending charges and convictions. Local practice may require such inquiries to be made in person, rather than by mail, and a copy of an authorization from the employee may be required by certain law enforcement agencies.

*DEA inquiries.* Inquiries supplying identifying information should also be furnished to DEA Field Division Offices along with written consent from the concerned individual for a check of DEA files for records of convictions. The Regional check will result in a national check being made by the Field Division Office.

[40 FR 17143, Apr. 17, 1975, as amended at 47 FR 41735, Sept. 22, 1982]

## **PART 1302—LABELING AND PACKAGING REQUIREMENTS FOR CONTROLLED SUBSTANCES**

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AUTHORITY: 21 U.S.C. 821, 825, 871(b), 958(e).

SOURCE: 36 FR 7785, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

### **§ 1302.01 Scope of Part 1302.**

Requirements governing the labeling and packaging of controlled substances pursuant to sections 1305 and 1008(d) of the Act (21 U.S.C. 825 and 958(d)) are set forth generally by those sections and specifically by the sections of this part.

[36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

### **§ 1302.02 Definitions.**

As used in this part, the following terms shall have the meanings specified:

(a) The term *commercial container* means any bottle, jar, tube, ampule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term *commercial*

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container does not include any package liner, package insert or other material kept with or within a commercial container, nor any carton, crate, drum, or other package in which commercial containers are stored or are used for shipment of controlled substances.

(b) The term *label* means any display of written, printed, or graphic matter placed upon the commercial container of any controlled substance by any manufacturer of such substance.

(c) The term *labeling* means all labels and other written, printed, or graphic matter (1) upon any controlled substance or any of its commercial containers or wrappers, or (2) accompanying such controlled substance.

(d) The term *manufacture* means the producing, preparation, propagation, compounding, or processing of a drug or other substance or the packaging or repackaging of such substance, or the labeling or relabeling of the commercial container of such substance, but does not include the activities of a practitioner who, as an incident to his administration or dispensing such substance in the course of his professional practice, prepares, compounds, packages or labels such substance. The term *manufacturer* means a person who manufactures a drug or other substance, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst.

(e) Any term not defined in this section shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or § 1301.02 of this chapter.

[36 FR 7785, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

### § 1302.03 Symbol required; exceptions.

(a) Each commercial container of a controlled substance (except for a controlled substance excepted by the Administrator pursuant to § 1308.31 of this chapter) shall have printed on the label the symbol designating the schedule in which such controlled substance is listed. Each such commercial container, if it otherwise has no label, must bear a label complying with the requirement of this part.

(b) Each manufacturer shall print upon the labeling of each controlled

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substance distributed by him the symbol designating the schedule in which such controlled substance is listed.

(c) The following symbols shall designate the schedule corresponding thereto:

Schedule	
Schedule I .....	CI or C-I.
Schedule II .....	CII or C-II.
Schedule III .....	CIII or C-III.
Schedule IV .....	CIV or C-IV.
Schedule V .....	CV or C-V.

The word "schedule" need not be used. No distinction need be made between narcotic and nonnarcotic substances.

(d) The symbol is not required on a carton or wrapper in which a commercial container is held if the symbol is easily legible through such carton or wrapper.

(e) The symbol is not required on a commercial container too small or otherwise unable to accommodate a label, if the symbol is printed on the box or package from which the commercial container is removed upon dispensing to an ultimate user.

(f) The symbol is not required on a commercial container containing, or on the labeling of, a controlled substance being utilized in clinical research involving blind and double blind studies.

[36 FR 7785, Apr. 24, 1971, as amended at 36 FR 18731, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

### § 1302.04 Location and size of symbol on label.

(a) The symbol shall be prominently located on the right upper corner of the principal panel of the label of the commercial container and/or the panel of the commercial container normally displayed to dispensers of any controlled substance listed in Schedules I through V. The symbol must be at least two times as large as the largest type otherwise printed on the label.

(b) In lieu of locating the symbol in the corner of the label, as prescribed in paragraph (a) of this section, the symbol may be overprinted on the label, in which case the symbol must be printed at least one-half the height of the label and in a contrasting color providing clear visibility against the background color of the label.

(c) In all cases the symbol shall be clear and large enough to afford easy identification of the schedule of the controlled substance upon inspection without removal from the dispenser's shelf.

**§ 1302.05 Location and size of symbol on labeling.**

The symbol shall be prominently located on all labeling other than labels covered by § 1302.04. In all cases the symbol shall be clear and large enough to afford prompt identification of the controlled substance upon inspection of the labeling.

**§ 1302.06 Effective dates of labeling requirements.**

(a) All labels on commercial containers of, and all labeling of, a controlled substance which is listed in any schedule on May 1, 1971, and which is packaged after December 1, 1971, shall comply with the requirements of § 1302.03.

(b) All labels on commercial containers of, and all labeling of, a controlled substance which either is listed in any schedule on May 1, 1971, and thereafter transferred to another schedule or is added to any schedule after May 1, 1971, and which is packaged more than 180 days following the date on which the transfer or addition becomes effective, shall comply with the requirements of § 1302.03.

(c) The Administrator may, in the case of any controlled substance, require compliance with the requirements of § 1302.03 within a period of time shorter than required by this section if he finds that public health or safety necessitate an earlier effective date.

(d) Until compliance is required under this section, the label on commercial container containing, and the labeling of, any controlled substance shall comply with any requirements under Federal law as to labels of such containers and as to labeling of such substances existing prior to the effective date prescribed in this section.

**§ 1302.07 Sealing of controlled substances.**

(a) On each bottle, multiple dose vial, or other commercial container of any

controlled substance listed in Schedules I or II or of any narcotic controlled substance listed in Schedule III or IV, there shall be securely affixed to the stopper, cap, lid, covering, or wrapper or such container a seal to disclose upon inspection any tampering or opening of the container.

(b) Any seal accepted for use under Federal law prior to May 1, 1971, shall be deemed acceptable for use under this section.

[36 FR 7785, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

**§ 1302.08 Labeling and packaging requirements for imported and exported substances.**

(a) The symbol requirements of §§ 1302.03–1302.06 apply to every commercial container containing, and to all labeling of, controlled substances imported into the jurisdiction of and/or the customs territory of the United States, as defined in § 1311.02 of this chapter.

(b) The symbol requirements of §§ 1302.03–1302.06 do not apply to any commercial containers containing, or any labeling of, a controlled substance intended for export from the jurisdiction of the United States, as defined in § 1311.02 of this chapter.

(c) The sealing requirements of § 1302.07 apply to every bottle, multiple dose vial, or other commercial container of any controlled substance listed in schedule I or II, or of any narcotic controlled substance listed in schedule III or IV, imported into, exported from, or intended for export from, the jurisdiction of and/or the customs territory of the United States, as defined in § 1311.02 of this chapter.

[36 FR 18731, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

## PART 1303—QUOTAS

Sec.

### GENERAL INFORMATION

1303.01 Scope of Part 1303.

1303.02 Definitions.